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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,803	12/14/2005	Daniel T. Green	022354-000310US	7164

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/540,803	GREEN ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending, as drawn to products and methods of the combinational use of insulin and glucagon in e.g. diabetic control. The aim of using glucagon with standard insulin diabetic therapy, is premised on counteracting the hypoglycemic states inherent in standard insulin therapy.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11, 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Houben et al. (US 6,572,542).

Houben et al. teach an infusion pump comprising insulin and glucagons, in a formulation, in amounts therapeutically effective for the control of diabetes and treatment (and some degree of prevention, though not 100%) of hypoglycemia in a human or other mammal, wherein the steps are intrinsically within one minute to twelve hours of each other depending on the patients insulin/hypoglycemic state as monitored by the system, intrinsically separately administered depending on the patients need for insulin or glucagons in response to the glycemic state; in a diabetic patient who treated prior to suffering from hypoglycemic symptoms based on controls for response prior to; wherein the formulation is an infusion pump; for parenteral administration

of insulin and/or glucagons; transdermally; comprising both insulin and glucagons; in a pump that controls administration of the respective drugs (entire document, especially e.g. claims 55-82; abstract; Figures 1-3; col. 2, lines 51-68).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 8, 10, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houben et al. (US 6,572,542) in view of Trading et al. (Europ. J. of Pharm., 7 (1969), 206-10) and Unger et al. (US 5,542,935).

Houben et al. is discussed above. Although Houben et al. generally contemplates any glucagons for infusion pump delivery, Houben et al. does not expressly recite "longer duration of action" glucagons (Applicant's claim 10). Additionally, although Houben et al. leaves open the containment of said glucagons in the infusion pump/formulations therein, Houben et al. does not expressly recite that if be in a liposomal and/or microsphere formulation (Applicant's claims 12-13).

Trading et al. teach the effectiveness of long acting (prolonged) glucagons for e.g. drug-induced (i.e. insulin-induced) hypoglycemia (title, col. 2, page 206).

Unger et al. teach improved formulation encapsulations for therapeutic agents such a glucagon, using microsphere, liposomal, and/or liposomal microsphere (col. 5, line 60; Fig. 8; col. 24, line 53).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use any glucagons, including long duration, in the insulin/glucagons formulations of the infusion pumps for treating hypoglycemia in Houben et al., because Trading et al. advantageously teach the effectiveness of long acting (prolonged) glucagons for e.g. drug-induced (i.e. insulin-induced) hypoglycemia, and one or ordinary skill in the art would have been motivated to use a glucagons capable of longer term effects over one which does not in the infusion pump therapy of Houben et al.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use any means of containing a formulation comprising glucagons, including long duration glucagon, in the insulin/glucagons formulations of the infusion pumps for treating hypoglycemia in Houben et al., because Unger et al. advantageously teach improved formulation encapsulations for therapeutic agents such a glucagon, using microsphere, liposomal, and/or liposomal microsphere, and one or ordinary skill in the art would have been motivated to use an improved means of formulation for containing any glucagon used in the infusion pump therapy of Houben et al.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Citation of Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bremer et al. (Ch. 9, cited in Protein Delivery-Physical Systems, 1997, Plenum Press, pages 248-9; cited in Applicant's IDS of 03/20/2006) teaches an infusion pump of insulin and glucagons, with 6 minute phase displacement, for the control of glucose levels. However, the study was only conducted on "normal humans", and did not expressly teach the pump in the treatment of diabetes or in a diabetic patient.

Claim Rejections - 35 U.S.C. § 112 1st Scope

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 5, and dependent claims 3-4, 6, and 8-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hypoglycemia using glucagons, does not reasonably provide enablement for *preventing* hypoglycemia using the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated/disclosed that glucagons may be used for treating hypoglycemia and/or reducing the risk thereof. However, the claims also encompass using glucagon to prevent hypoglycemia, which is clearly beyond the scope of the instantly disclosed/claimed invention and the teachings or rather limitations in the art as to treatment regimens involving the use of glucagon in the treatment regimen surrounding the dynamic state of hypoglycemia/insulin balance (see any generally known teachings on the diabetic difficulty in regulation e.g. Houben et al. (US 6,572,542) reacting to and then treating hypoglycemic states, but not wholly preventing some degree of hypoglycemia (e.g. claims)). Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does the term "treat"/discouraging, especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing hypoglycemia (which clearly is not recognized in the medical art as being a totally preventable condition).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the claimed composition which would function to wholly prevent hypoglycemia using glucagon.

Observation

In claim 14, line 6, there are a number of extra spaces between the words "pulmonary" and "administration". Applicant may wish to correct, should any amendments be filed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA 06/09/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654